

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-441

APPROVED DRAFT LABELING

(this copy not intended to meet Drug Facts requirements per 21 CFR 201.66)

Advil®
Allergy Sinus

(10s, 20s + 40s Cartons and Pouch Dispenser)

Ibuprofen 200 mg ~~Advil~~ Pain Reliever/Fever Reducer
Pseudoephedrine HCL 30 mg ~~Advil~~ Nasal Decongestant
Chlorpheniramine Maleate ~~Advil~~ Antihistamine

Only 1 pill every 4-6 hours

Relieves Runny Nose, Nasal Congestion,
Sneezing, Itchy, Watery Eyes,
Headache and Sinus Pressure

10
Coated
Caplets*
*Capsule-Shaped Tablets

Drug Facts

Active ingredients (in each caplet)

Chlorpheniramine maleate 2 mg.....	Antihistamine
Ibuprofen 200 mg.....	Pain reliever/fever reducer
Pseudoephedrine HCl 30 mg.....	Nasal decongestant

Purposes

Uses

- temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold:
- | | | |
|--------------|-------------------------|---------------------------------|
| • runny nose | • itchy, watery eyes | • itching of the nose or throat |
| • sneezing | • nasal congestion | • sinus pressure |
| • headache | • minor aches and pains | • fever |

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction which may include:

- hives • facial swelling • asthma (wheezing) • shock

Taking more than recommended may cause stomach bleeding.

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take ibuprofen or other pain relievers/fever reducers. Ibuprofen may cause stomach bleeding.

Do not use if you

- have ever had an allergic reaction to any other pain reliever/fever reducer
- are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- heart disease • high blood pressure • thyroid disease • diabetes • kidney disease
- ulcers • bleeding problems • glaucoma
- problems or serious side effects from taking pain relievers or fever reducers
- stomach problems that last or come back, such as heartburn, upset stomach, or pain
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking sedatives or tranquilizers
- over 65 years of age
- taking any other product that contains ibuprofen, or any other pain reliever/fever reducer
- taking any other product that contains pseudoephedrine, chlorpheniramine or any other nasal decongestant or antihistamine
- taking a prescription drug for anticoagulation (blood thinning), or a diuretic
- taking any other drug

APPEARS THIS WAY
ON ORIGINAL

Drug Facts (continued)
When using this product <ul style="list-style-type: none"> do not use more than directed avoid alcoholic drinks be careful when driving a motor vehicle or operating machinery drowsiness may occur take with food or milk if stomach upset occurs alcohol, sedatives, and tranquilizers may increase drowsiness
Stop use and ask a doctor if <ul style="list-style-type: none"> an allergic reaction occurs. Seek medical help right away. nasal congestion lasts for more than 7 days fever lasts for more than 3 days you get nervous, dizzy, or sleepless symptoms continue or get worse stomach pain occurs with the use of this product even if mild pain persists any new symptoms appear
<p>If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use this product during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>
Directions <ul style="list-style-type: none"> adults: take 1 caplet every 4-6 hours while symptoms persist. do not take more than 6 caplets in any 24-hour period, unless directed by a doctor children under 12 years of age: consult a doctor
Other information <ul style="list-style-type: none"> read all warnings and directions before use. Keep carton store in a dry place 20-25°C (68-77°F) avoid excessive heat above 40°C (104°F)
Inactive ingredients carnauba wax, croscarmellose sodium, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, glyceryl behenate, hypromellose, iron oxide black, microcrystalline cellulose, polydextrose, polyethylene glycol, pregelatinized starch, propylene glycol, silicon dioxide, starch, titanium dioxide

Product inside sealed in plastic blister with foil backing.
Do Not Use if plastic blister or foil backing is broken.

Wyeth Consumer Healthcare
Madison, NJ 07940 Made in U.S.A.
U.S. Patent Nos. 4,619,934 and 5,025,01
Appearance of the orange Advil® Allergy Sinus caplet
S a trademark of Wyeth Consumer Healthcare

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